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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,015	05/15/2002	Masayoshi Maki	56687(71526)	7186
21874	7590	10/31/2003	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 9169 BOSTON, MA 02209			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	7
DATE MAILED: 10/31/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/030,015

Applicant(s)

MAKI ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

Examiner acknowledges receipt of priority document, IDS and response, all filed 05/15/2002.

#### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d), a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

#### ***Claim Objections***

4. Claims 4 and 5 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

5. The use of parenthetical expression in claim 1 may be avoided. The terms in the parenthesis may be deleted.

6. In claim 4, line 2, the comprising before "further" may be deleted.

*Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamanaka et al. (US 5,176,916).

Yamanaka discloses a medical adhesive that comprises 0.1 to 15 % of medicinal ingredient in a hydrophobic base polymer (abstract, column 2, lines 60-68 and claims 1 and 14); norethisterone is one of the medicinals that can be incorporated in the polymer base (column 6, line 36); the hydrophobic polymer is used in an amount ranging from 25 to 80% and styrene-isoprene-styrene block copolymer is an example of the hydrophobic polymer (claims 1 and 14).

Instant claims 1 and 2 recite the property of the adhesive composition and the property of a composition cannot be separated from the composition. The teaching of Yamanaka meets the limitations of the claims.

9. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Oda et al. (US 5,725,874).

Oda discloses percutaneously absorbable preparations that comprise 20% styrene-isoprene-styrene block copolymer, polyisobutylene, liquid paraffin, rosin ester derivative, and 1% norethisterone (examples 44 and 45). The rosin ester derivative is 17% and 30% examples 44 and 45 respectively. Liquid paraffin, which is equivalent to the softener of instant claim 5 is

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47% and 25% in examples 44 and 45 respectively. In examples 40 and 41, estradiol is the hormone active agent.

Instant claims 1 and 2 recite the property of the adhesive composition and the property of a composition cannot be separated from the composition. The teaching of Oda meets the limitations of the claims.

10. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Hirano et al. (EP 0 976 405).

Hirano discloses a composition that comprises styrene-isoprene-styrene block copolymer, a softening agent and an adhesive resin and hexylene glycol and a medicine (abstract). Estradiol, 0.1% in example 1, 5% in example 2 and 1% in example 3; norethisterone acetate, 0.5% in example 1, 10% in example 2 and 2% in example 3 are examples of medicines incorporated in the composition of Hirano. The adhesive amount in Hirano's composition ranges from 27% to 40% (examples 1-3). Liquid paraffin, which is a softener ranges from 10-60% (examples 1-3). Specifically, Hirano page 3, lines 39-42, discloses that norethisterone is an active agent for the composition.

Instant claims 1 and 2 recite the property of the adhesive composition and the property of a composition cannot be separated from the composition. The teaching of Hirano meets the limitations of the claims.

Applicants cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

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11. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirano et al. (JP 11001441).

Hirano discloses a composition comprising 10-30% styrene-isoprene-styrene block copolymer, 10-60% liquid paraffin softening agent, 20-60% tackifying resin (adhesives resin) and 1-10% hexylene glycol (English abstract).

Instant claims 1 and 2 recite the property of the adhesive composition and the property of a composition cannot be separated from the composition. The teaching of Hirano meets the limitations of the claims.

Applicants cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirano et al. (EP 0 976 405).

Hirano clearly teaches the instant adhesive composition except that in the examples the progesterone taught is norethisterone. However, on page 3, line 42, Hirano discloses that

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norethisterone are norethisterone acetate are equivalent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare an adhesive composition that comprises styrene-isoprene-styrene block copolymer, a softening agent and an adhesive resin and hexylene glycol and estradiol and norethisterone acetate according to the examples in Hirano. One having ordinary skill in the art would have been motivated to substitute norethisterone for norethisterone acetate with the expectation that the composition will function as the composition that has the norethisterone acetate since the two are equivalent.

14. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

  
Blessing Fubara  
Patent Examiner  
Tech. Center 1600